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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,510	06/26/2000	JOHN P. HELGESON	WARF H108	6417
7590	02/18/2004		EXAMINER	
Janet E. Reed, Esq. WOODCOCK WASHBURN LLP One Liberty Place 46th Floor Philadelphia, PA 19103				KRUSE, DAVID H
				ART UNIT 1638
				PAPER NUMBER DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,510	HELGESON ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 November 2003.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1, 5, 6, 8, 9, 16, 17 and 19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 8 and 9 is/are allowed.
 6) Claim(s) 1, 5, 6, 16, 17 and 19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 3 November 2003 has been entered.

STATUS OF THE APPLICATION

2. Claims 4, 7 and 18 have been cancelled as requested in Applicant's reply received in the Office on 3 November 2003.
3. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 1, 5, 6 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1 and 17, "a DNA segment that hybridizes with one or more of" renders the claims indefinite because it is unclear what the metes and bounds of "hybridizes with" are in the instant case. In addition, nucleic acids having the sequence of SEQ I D

NO: 3, 4 or 5, taught as CT88 RFLP markers appear to not teach the metes and bounds of a gene that confers resistance to late blight. Claims 5 and 6 are also rejected because they do not obviate the indefiniteness of claim 1.

6. Claims 1, 5, 6, 16, 17 and 19 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 June 2003. Applicant's arguments filed 3 November 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification describes the claimed subject matter by disclosing the mapping of one genetic source of late blight resistance in *S. bulbocastanum* to chromosome 8, and its association with at least two RAPD markers and five RFLP markers, the physical sequences of which are either disclosed in the specification or are readily available in the literature (the latter being the case for RFLPs CT148, CT252 and CT68), and that the specification further discloses the production of somatic hybrids of *S. tuberosum* and *S. bulbocastanum* and numerous backcross progeny thereof wherein the presence of late blight resistance is at least 95% correlated with the presence of one or more of the RAPD or RFLP markers (page 5, last paragraph of the Remarks). This argument is not found to be persuasive because it remains unclear that the process of making adequately describes the genus as broadly claimed.

In the Helgeson Declaration filed under 37 C.F.R. § 1.132, on 3 November 2003, Dr. Helgeson states that not all accessions of *S. bulbocastanum* are identical and that some are resistant to various diseases and other are susceptible (page 5 of the Helgeson Declaration). Hence, because the gene(s) that confers resistance to late blight has not been described, a potato plant comprising a segment of chromosome 8 of *S. bulbocastanum*, even identified with the exemplified RAPD and RFLP markers, does not adequately describe the invention as broadly claimed (see pages 12-13 of the specification which speculates on the eventual cloning of the disease resistance-conferring gene(s) of *S. bulbocastanum*).

Applicant argues that sufficient information has been conveyed in the present specification such that those of skill in the art would recognize the description of the late blight-resistant potato plants as claimed, in particular, the specification discloses functional information, as well as structural information required for the skilled artisan to correlate the function with known structures - i.e., the presence of the relevant portion of *S. bulbocastanum* chromosome 8 as evidenced by one or more linked RAPD or RFLP markers (page 6, 1st paragraph of the Remarks). This argument is not found to be persuasive as outlined above, that not all accessions of *S. bulbocastanum* are identical and that some are resistant to various diseases and other are susceptible.

7. Claims 1, 5, 6, 16, 17 and 19 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the somatic hybrid potato plants produced by somatic hybridization between *Solanum tuberosum* and *Solanum bulbocastanum* as set forth at Table 3 on page 24 of the specification, does not

reasonably provide enablement for any potato plant comprising a segment of chromosome 8 of *Solanum bulbocastanum* which comprises a gene that confers resistance to late blight or a transformed potato plant that is late blight resistant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 June 2003. Applicant's arguments filed 3 November 2003 have been fully considered but they are not persuasive.

Applicant argues that the present specification teaches a late blight-resistant potato plant produced by a combination of (1) somatic hybridization between *S. tuberosum* and *S. bulbocastanum* and (2) traditional breeding methods comprising backcrossing with *S. tuberosum* and selecting progeny having disease resistance co-segregating with a physical marker comprising a RFLP or RAPD fragment sequence associated with the relevant portion of *S. bulbocastanum* chromosome 8, and that the specification further teaches that these somatic hybrids and their progeny were resistant to potato early blight and *Verticillium* wilt, as well as late blight (page 6, 3rd paragraph of the Remarks). This argument is not found to be persuasive because as outlined above, the Helgeson Declaration filed under 37 C.F.R. § 1.132, on 3 November 2003, Dr. Helgeson states that not all accessions of *S. bulbocastanum* are identical and that some are resistant to various diseases and other are susceptible (page 5 of the Helgeson Declaration). Hence, because the gene(s) that confers resistance to late blight has not been described, a potato plant comprising a segment of chromosome 8 of *S.*

bulbocastanum, even identified with the exemplified RAPD and RFLP markers, does not adequately teach how to make and use the invention as broadly claimed.

Applicant argues that one of skill in the art would recognize that the inventors were in possession of the invention at the filing date, and would be enabled to practice the invention through study of the specification because (1) teaching within the specification of how to make the claimed potato plants and discern that they contain the relevant portion of *S. bulbocastanum* chromosome 8, (2) the fact that RAPD and RFLP markers define physical locations within a chromosome of a given plant species and can be used to pinpoint the physical location of genes that co-segregate with them, (3) teaching in the specification that plants produced by the described methods were also resistant to early blight and *Verticillium* wilt, and (4) the fact that the RAPD and RFLP markers identified and used in the invention also proved to be useful for cloning the late blight resistance gene from *S. bulbocastanum* chromosome 8 (page 7, 1st paragraph of the Remarks). This argument is not found to be persuasive for the reasons given above. In view of the Helgeson Declaration, it is unclear if the instant invention requires unique starting materials, specifically a specific *S. bulbocastanum* plant, in order to practice the claimed invention. In such a case, an enabling deposit of biological material would be required to make and use the invention as broadly claimed without undue trial and error experimentation. The examiner notes that the Specification only teaches the use of a single *S. bulbocastanum* plant, PI 243510 (page 14, 1st paragraph of the specification).

Claim Rejections - 35 USC § 102

8. Claims 1, 6, 16 and 17 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Schumann *et al.* (1991, *Physiologia Plantarum*, 82: A23, Abstract 134, December) taken with the evidence of Naess *et al* (2000, *Theor. Appl. Genet.* 101:697-704). This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 June 2003. Applicant's arguments filed 3 November 2003 have been fully considered but they are not persuasive.

Applicant argues that the mere fact that the late blight-resistance in the hybrids disclosed by Naess *et al.* was traced to *S. bulbocastanum* chromosome 8 does not necessarily mean that the late blight resistance in the hybrids of Schumann *et al.* was conferred by any portion of *S. bulbocastanum* chromosome 8 or, for that matter, by *S. bulbocastanum* at all (paragraph spanning pages 7-8 of the Remarks). This argument is not found to be persuasive because it was well known in the art at the time of Applicant's invention that *S. bulbocastanum* has broad, horizontal, resistance to *P. infestans* (late blight), which Applicant states in the specification on page 4, 2nd paragraph.

Applicant argues that the germplasms used by Schumann *et al.* were not disclosed, and that not all *S. bulbocastanum* germplasms contain the resistance-conferring gene on chromosome 8 and that experimental evidence generated by Dr. Helgeson's laboratory revealed that one *S. bulbocastanum* germplasm conferred some "improved" resistance to late blight, but it was of a different type than that conferred by the DNA segment on chromosome 8, and did not contain the relevant portion of

chromosome 8 identifiable by the presence of the RAPD and RFLP markers and therefore, it would be impossible for one of skill in the art to know from what source the "improved" resistance of the Schumann *et al.* hybrids was derived (page 8, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the Helgeson Declaration provides no evidence that the *S. bulbocastanum* used by Schumann *et al.* does not inherently comprise the resistance gene on chromosome 8, in addition, the *S. bulbocastanum* PI 243510 variety used by Applicant has been widely available since 1957 in the United States.

Applicant argues that at paragraphs 13 and 14 of the Declaration, Dr. Helgeson points out that late blight resistance can also be found in certain germplasms of potato (*S. tuberosum*) and that without knowing the source of potato used by Schumann *et al.*, it would be impossible for one skilled in the art to determine if the "improved" resistance of the Schumann *et al.* hybrids arose from *S. tuberosum* or *S. bulbocastanum*.

Applicant also argues that in contrast, the biological materials used in the present invention were clearly identified, and the disease-conferring portion of *S. bulbocastanum* chromosome 8 was linked to several identifiable markers, such that anyone of skill in the art could produce somatic hybrids and select progeny containing the chromosomal segment and exhibiting late blight resistance (page 8, 3rd paragraph of the Remarks). These arguments are not found to be persuasive because it is clear from the disclosure of Schumann *et al.* that the intent was to ingress late blight resistance from *S. bulbocastanum* and not *S. tuberosum*. Applicant's argument that the biological materials used in the present invention were clearly identified, and the disease-

conferring portion of *S. bulbocastanum* chromosome 8 was linked to several identifiable markers is not relevant to an argument of inherency, the identification of a property inherent in the prior art product does not distinguish the claimed product from the prior art.

Applicant argues that at paragraph 15 of his Declaration, Dr. Helgeson points out that the hybrids disclosed by Schumann *et al.* were likely not even fertile, and therefore could not be used to produce disease resistant progeny as taught and presently claimed (page 8, 4th paragraph of the Remarks). This argument is not found to be persuasive because there is no indication that the hybrid plants of Schumann *et al.* were completely sterile. It was known in the art at the time of Applicant's invention that somatic hybrids between *S. tuberosum* and *S. bulbocastanum* are sometimes male sterile but that they could readily be crossed as the female parent with *S. tuberosum* to produce progeny (see Masuelli *et al* 1995, Theor. Appl. Genet. 91: 401-408, at page 402, left column under Materials and Methods. The Masuelli *et al* disclosure was submitted with the Application on 24 January 2000).

Finally, Applicant argues that the information set forth in Declaration of Dr. Helgeson, as well as the arguments previously asserted, it clearly cannot be said that the resistance observed in the hybrids of Schumann *et al.* necessarily arose from *S. bulbocastanum* chromosome 8 and that the fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic (page 8, 5th paragraph of the Remarks). This argument is not found to be persuasive for the reasons given *supra* because it is clear from the disclosure of

Schumann *et al.* that the late blight resistance was being inherited from *S. bulbocastanum* and not *S. tuberosum*, that the desirable late blight resistance of *S. bulbocastanum* lies on chromosome 8 as disclosed by Naess *et al*, and that without evidence to the contrary, the instant claims have been previously disclosed by Schumann *et al.* See *In re Best* 562F.2d 1252 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

9. Claims 1, 5, 6, 16, 17 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by James *et al* 1995 (*Phytopathology* 85(10): 1195, Abstract No. 648) taken with the evidence of Naess *et al* (2000, *Theor. Appl. Genet.* 101:697-704).

James *et al* disclose *Solanum bulbocastanum* + *S. tuberosum* somatic hybrids and backcrossed progeny having late blight resistance and early blight resistance. The somatic hybrids and backcrossed progeny would inherently comprise a segment of chromosome 8 of the genome of *Solanum bulbocastanum* which comprises a gene that confers said resistance to late blight in view of the evidence of Naess *et al*. Hence James *et al* have previously disclosed all of the claim limitations.

Conclusion

10. Claims 8 and 9 are allowed.
11. Claims 1, 5, 6, 16, 17 and 19 remain rejected.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse
AU 1638

David H. Kruse, Ph.D.
6 February 2004

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